

To: The Palliative Care Field

Re: FDA Announces the Approval of Morphine Sulfate Oral Solution for Relief of Acute and Chronic Pain

The U.S. Food and Drug Administration (FDA) has approved Morphine Sulfate Oral Solution for the relief of moderate to severe, acute and chronic pain in opioid-tolerant patients. The solution will be available in 100 milligrams per 5 mL or 20 milligrams per 1 mL.

Although using this medication to manage pain has been common practice for many years, this form and concentration of morphine was not FDA-approved until now. CAPC welcomes the news of the approval, as the morphine solution is critical for treating and preventing extreme suffering for those nearing the end of life.

In the spring of 2009, the FDA announced that it was ordering manufacturers to stop making the medication, as well as several other opioid medications that were developed so long ago they did not have FDA approval. After a huge outcry from CAPC, AAHPM, HPNA and NHPCO, the FDA reversed their decision. They agreed to keep morphine sulfate oral solution on the market in the 20 milligrams per 1 mL concentration until there was an approved version or an equivalent therapy.

As part of the FDA's unapproved drugs initiative, the FDA is working with the manufacturer of the now-approved product, Roxane Laboratories, to ensure that there is enough drug available for patients. The FDA will also be working with patient organizations and prescribers so that they are aware that an approved product is available, and can notify the FDA if there are any problems with availability.

The FDA continues to be concerned that the marketed drugs meet current FDA standards. For this formulation of morphine, the manufacturer developed a safety program prior to approval to address the known risks of morphine misuse, abuse and overdose. The new approval does not change the status of other painkillers that are highly beneficial to hospice and palliative care patients.

Learn More:

[FDA News Release](#)

[March 31, 2009 Warning Letters, companies, and affected products](#)

[List of FDA-approved drug products](#)

[FDA Threatens Opioids](#)

[Associated Press, April 2009](#)

Thank you,

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